

TECHNICAL SHEET IDYLLA™ KRAS MUTATION TEST



The **Idylla™ KRAS Mutation Test**, performed on the Biocartis Idylla™ system, is an *in vitro* diagnostic Test for the qualitative detection of 21 mutations in **codons 12, 13, 59, 61, 117 and 146** of the *KRAS* gene. The Idylla™ KRAS Mutation Test, from **sample-to-result**, starts with formalin-fixed paraffin-embedded (FFPE) human tissue from metastatic colorectal cancers to liberate DNA for subsequent real-time PCR amplification and detection.

FEATURES

KRAS mutation detection		
Codon 12 (exon 2)	G12C	(c.34G>T)
	G12R	(c.34G>C)
	G12S	(c.34G>A)
	G12A	(c.35G>C)
	G12D	(c.35G>A)
	G12V	(c.35G>T)
Codon 13 (exon 2)	G13D	(c.38G>A)
Codon 59 (exon 3)	A59E	(c.176C>A)
	A59G	(c.176C>G)
	A59T	(c.175G>A)
Codon 61 (exon 3)	Q61K	(c.181C>A; c.180_181delinsAA)
	Q61L	(c.182A>T)
	Q61R	(c.182A>G)
	Q61H	(c.183A>C; c.183A>T)
Codon 117 (exon 4)	K117N	(c.351A>C; c.351A>T)
Codon 146 (exon 4)	A146P	(c.436G>C)
	A146T	(c.436G>A)
	A146V	(c.437C>T)

KRAS Total (acting as Sample Processing Control)

Specimen requirements	
Sample Type	FFPE tissue sections (5 to 10 µm)
Neoplastic cells	≥10%, if less macrodissection is required
Tissue area	50-600 mm ² (5 µm) 25-300 mm ² (10 µm)

Performance	
Analytical Sensitivity	LOD ≤5% for all KRAS mutations

Between Laboratory Reproducibility
(480 results at 3 sites)

100% agreement for 5% KRAS G12D
100% agreement for 5% KRAS G12S
100% agreement for 5% KRAS G12V
100% agreement for 50% KRAS G13D

Between Lot Reproducibility
(375 results on 3 lots)

100% agreement for 5% KRAS G12A
100% agreement for 5% KRAS G12D
100% agreement for 5% KRAS G12S
100% agreement for 5% KRAS G12V
100% agreement for 5% KRAS G13D

Total turnaround time

Time 120 minutes

ACCURACY - CLINICAL PERFORMANCE EVALUATION

96.7% overall percent agreement was obtained during the clinical performance evaluation comparing Idylla™ with a reference method based on RT-PCR.

96.7% overall concordance

		Reference test								
		G12A	G12C	G12D	G12R	G12S	G12V	G13D	No mutation	Total
Idylla™ KRAS Mutation Test	G12A	6								6
	G12C		6							6
	G12D			25						25
	G12R				3				1*	4
	G12S					6				6
	G12V					1	15		1*	17
	G13D					1		16	3*	20
	No mutation	1*							97	98
A59E/G/T									1	1
Q61H/H2									3	3
Q61K/K2										0
Q61L/R										0
K117N/N2			1						2	3
A146T/V/P							1		4	5
Totals		7	7	25	3	8	16	16	112	194

Note: the Reference test is not designed to pick up mutations in codon 59, 61, 117 and 146

* Due to limitations in available material (n=2) or insufficient DNA quality (n=3), only one of the 6 discordant results could be resolved; NGS confirmed the G12V result called by Idylla™

MULTI-CENTER EVALUATION OF THE FULLY-AUTOMATED PCR-BASED IDYLLA™ KRAS MUTATION ASSAY FOR RAPID KRAS MUTATION STATUS DETERMINATION ON FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE OF HUMAN COLORECTAL CANCER.

Solassol J. et al. PLOS ONE 2016.

		95.9% overall concordance							Routine reference methods*	
		Codon 12	Codon 13	Codon 59	Codon 61	Codon 117	Codon 146	No mutation	Total	
Idylla™ KRAS Mutation Assay	Codon 12	138						3	141	
	Codon 13		38						38	
	Codon 59			5					5	
	Codon 61	1			14			5	20	
	Codon 117					4			4	
	Codon 146						18	1	19	
	No mutation	3	2				1	129	135	
	TOTAL	142	40	5	14	4	19	138	362	

Mutations not picked up by Idylla™ or the reference method (n=8) are not included in the % agreement calculation. Idylla does not pick up the following low prevalent (<1%) mutations: 4xG13C, 1xG13R, 1xG12F (samples excluded from table). Roche Cobas does not pick up mutations in codon 146 (2x).

* Different reference methods were used: cobas® KRAS Mutation Test (Roche), Ion Torrent AmpliSeq™ Colon and Lung Cancer Research Panel (Life Technologies), theascreen® KRAS Pyro® Kit (Qiagen), theascreen® RAS Extension Pyro Kit (Qiagen), HRM screening and pyrosequencing, Sanger sequencing, HRM screening and Sanger sequencing; for the analysis, when Idylla™ identified a specific mutation in codon 12, 13 or 61, and the cobas® KRAS Mutation Test (Roche) reported a "codon 12/13" or "codon 61" result, both results were considered identical.



Discordant analysis by ddPCR, Idylla™ retest and NGS

		98.9% overall concordance							Routine reference methods, including further analysis by ddPCR, Idylla™ retest, NGS	
		Codon 12	Codon 13	Codon 59	Codon 61	Codon 117	Codon 146	No mutation	Total	
Idylla™ KRAS Mutation Assay	Codon 12	142							142	
	Codon 13		38						38	
	Codon 59			5					5	
	Codon 61	1			15			1	17	
	Codon 117					4			4	
	Codon 146						20		20	
	No mutation	1	2					133	136	
	TOTAL	144	40	5	15	4	20	134	362	

IDYLLA™ KRAS PUBLICATIONS

Check our website: <https://www.biocartis.com/publications/articles-posters?cat=19> and subscribe to receive our newest publications.



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